Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 074897 0011 Rev. 02

Manufacturer:

NINGBO HI-TECH UNICMED IMP. & EXP. CO., LTD.
11/F, GREEN TOWN LVYUAN TOWER
588 CANGHAI ROAD
315040 NINGBO
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Wound Drainage System With and without Trocar, Suction Catheters, Stomach Tubes, Oxygen Mask With Reservoir Bag, Nasal Cannula, Suction Connection Tube With Yankauer Handle, Nebulizer Mask, Blood Lancets, Simple Oxygen Mask, Disposable Surgical Blades(with and without handle), Digital Thermometers, C.P.R. Mask, Blood Pressure Monitors, Tracheal Tubes, Reinforced Endotracheal Tubes, Disposable Air Cushion Face Masks, Laryngeal Mask Devices, Sterile Latex Surgical Gloves, Vacuum Blood Collection Needles for Single use.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19635EXT01

Valid from: 2019-09-23
Valid until: 2024-05-26

Date, 2019-09-23

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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